510(k) Summary

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K100464

Applicant Information:

Name:
Wako Chemicals, USA, Inc.
Wako Diagnostics

USA Headquarters Address:
1600 Bellwood Road
Richmond, VA 23237

Contact:

Martha Murari, Ph.D., RAC
Manager, Regulatory Affairs
Wako Chemicals, USA, Inc.
Wako Diagnostics
1025 Terra Bella Ave., Suite A
Mountain View, CA 94043
Phone: (650) 210-9153 Ext. 133
Fax: 650-210-9170

Peter Panfili, Ph.D.
General Manager
Wako Chemicals, USA, Inc.
Wako Diagnostics
1025 Terra Bella Ave., Suite A
Mountain View, CA 94043
(650) 210-9153 Ext. 109
Fax: 650-210-9170

Hiroyuki Yamada, M.S.
Manager, Clinical Research
Wako Chemicals, USA, Inc.
Wako Diagnostics
1025 Terra Bella Ave., Suite A
Mountain View, CA 94043

Lori Creasy, RAC
Regulatory Specialist
Wako Chemicals, USA, Inc.
Wako Diagnostics
1600 Bellwood Road
Richmond, VA 23237

Date Prepared:
February 14, 2011

Device Information:

Primary Trade Names:
µTASWako i30 Immunoanalyzer System with
µTASWako AFP-L3 Immunological Test System and
µTASWako DCP Immunological Test System

µTASWako AFP-L3 Calibrator Set, µTASWako AFP-L3 Control L, and
µTASWako AFP-L3 Control H

µTASWako DCP Calibrator Set, µTASWako DCP Control L, and
µTASWako DCP Control H

Primary Classification Name:

AFP-L3% Immunological Test System	21 CFR §866.6030

Predicate Devices:
The µTASWako AFP-L3 Immunological Test System, including the associated calibrators and controls, was previously cleared as LBA AFP-L3 for use with the LiBASys instrument under K041847 and was assigned product code NSF for the system in its entirety.

The µTASWako DCP Immunological Test System, including the associated calibrators and controls, was previously cleared as LBA DCP for use with the LiBASys instrument under K062368 and was assigned product code OAU for the reagent. The product codes assigned for calibrators and controls were JIT and JJX, respectively.

Device Description:
The µTASWako i30 Immunoanalyzer System is a fully automated immunoassay system that can perform assays of the µTASWako AFP-L3 and µTASWako DCP Immunological Test Systems. This system automatically conducts sampling, mixing, separation, and fluorescence detection on a microfluidic chip to achieve high sensitivity and accuracy. The instrument contains an automated liquid dispenser, temperature controlled reagent container, chip station, analysis compartment, and sample rack station. The outside panel has a printer and a touch panel with a menu to order measurements and to check the availability for reagent, chip, wash solution, and pure water. A chip is used for each test and is disposable. The instrument is designed to automatically and constantly monitor the reagents, chips, dispensing system and the measurement process so that measurement results are not given when an error occurs.

The system is comprised of the following products:

µTASWako i30
µTASWako AFP-L3, Calibrator Set, Control L and Control H
µTASWako DCP, Calibrator Set, Control L and Control H
Instrument and assay accessories as per labeling

Intended Use/ Indications for Use Statement:
The statements for the µTASWako AFP-L3 and µTASWako DCP Immunological Test Systems, the µTASWako i30 Immunoanalyzer System, and the Calibrator Set and Controls for each test system are as follows:

Indications for Use for the Wako µTASWako AFP-L3 Immunological Test System:
The µTASWako AFP-L3 Immunological Test System is an *in vitro* device that consists of reagents used with the µTASWako i30 Immunoanalyzer to quantitatively measure, by immunochemical techniques, AFP-L3% in human serum. The device is intended for *in vitro* diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma (HCC) in conjunction with other laboratory findings, imaging studies and clinical assessment. Patients with elevated AFP-L3% values (≥ 10%) have been shown to be associated with an increase in the risk of developing HCC within the next 21 months and should be more intensely evaluated for evidence of HCC according to the existing HCC practice guidelines in oncology.

continued

Indications for Use for the Wako µTASWako DCP Immunological Test System:
The µTASWako DCP Immunological Test System is an *in vitro* device that consists of reagents used with the µTASWako i30 Immunoanalyzer to quantitatively measure, by immunochemical techniques, DCP in human serum. The device is intended for *in vitro* diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma (HCC) in conjunction with other laboratory findings, imaging studies, and clinical assessment.

Indications for Use for the Wako µTASWako i30 Immunoanalyzer System:
The µTASWako i30 Immunoanalyzer is an in vitro diagnostic automated instrument intended for use to quantitatively measure analytes in clinical chemistry by immunochemical techniques. The µTASWako i30 Immunoanalyzer is indicated for use by healthcare professionals. It is intended for assays cleared or approved for use on this instrument.

Indications for Use for the Wako µTASWako AFP-L3 Calibrator Set, the Wako µTASWako AFP-L3 Control L, and the Wako µTASWako AFP-L3 Control H:
The Wako µTASWako AFP-L3 Calibrator Set is designed to be used with the Wako µTASWako AFP-L3 Immunological Test System for the quantitative determination of AFP-L3% in human serum.

The Wako µTASWako AFP-L3 Control L is designed to be used as quality control material for the quantitative determination of AFP-L3% in human serum using the Wako µTASWako AFP-L3 Immunological Test System.

The Wako µTASWako AFP-L3 Control H is designed to be used as quality control material for the quantitative determination of AFP-L3% in human serum using the Wako µTASWako AFP-L3 Immunological Test System.

Indications for Use for the Wako µTASWako DCP Calibrator Set, the Wako µTASWako DCP Control L, and the Wako µTASWako DCP Control H:
The Wako µTASWako DCP Calibrator Set is designed to be used with the Wako µTASWako DCP Immunological Test System for the quantitative determination of DCP in human serum.

The Wako µTASWako DCP Control L is designed to be used as a quality control material for the quantitative determination of DCP in human serum using the Wako µTASWako DCP Immunological Test System.

The Wako µTASWako DCP Control H is designed to be used as a quality control material for the quantitative determination of DCP in human serum using the Wako µTASWako DCP Immunological Test System.

Brief Summary of Technological Characteristics:

The following table briefly outlines technological characteristics of the Subject Device in comparison to the legally marketed predicate devices.

Characteristic	Comparison of Subject and Predicate Devices	µTASWako i30 System used with µTASWako AFP-L3 and µTASWako DCP Test Systems (Subject Device)	LiBASys System used with LBA AFP-L3 and LBA DCP Test Systems (Predicate Device)
Analytes Assayed	Same	AFP/AFP-L3%, DCP	AFP/AFP-L3, DCP
Mode of Operation	Same	Automated fluorescence analyzer	Automated fluorescence analyzer
Test Principle	Similar Rationale: i30 technology requires fluorescent dye	Fluorescence liquid-phase binding immunoassay system	Fluorescence liquid-phase binding enzyme immunoassay system
Operation Methodology	Similar Rationale: Although the separation methodologies are different, test principle remains the same.	Quantitative, fluorescence immunoassay, electrophoresis separation	Quantitative, fluorescence immunoassay, chromatographic separation
Fluorescence Technology	Different Rationale: i30 technology does not use enzyme-linked fluorescence detection.	Light Source: Diode laser (638 nm) Detector: Photo Diode Detector	Light Source: Deuterium Lamp Detector: Photometric Detector
Sample Matrix	Same	Human Serum	Human Serum
Reference Standard	Same	1st international standard for alpha-fetoprotein from NIBSC recognized by WHO	1st international standard for alpha-fetoprotein from NIBSC recognized by WHO

Summary of Performance Data:

(1) Sensitivity:
The analytical sensitivity for the AFP-L3 and DCP assays was determined as the limit of detection, the point at which the analytes are distinguished from blank. The LoD for AFP-L1 and AFP-L3 was found to be 0.030 ng/mL and 0.028 ng/mL, respectively. The LoD for DCP was found to be 0.042 ng/mL.

(2) Linearity/ Assay Reportable Range:
Linearity for the AFP-L3 and DCP assays was evaluated following a linear regression analysis and 95% confidence intervals of the data points. Full assay linearity was demonstrated over the claimed reportable ranges of 0.3.– 1000 ng/mL for Total AFP and of 0.5 – 99.5% for AFP-L3%. Full assay linearity was demonstrated over the claimed reportable range of 0.1 – 950 ng/mL for DCP.

(3) High Dose Hook Effect:
A high dose hook effect study demonstrated no effect of high concentration of Total AFP, up to 1,272,000 ng/mL, for the quantitative AFP-L3 assay. A high dose hook effect study demonstrated no effect of high concentration of DCP, up to 23,000 ng/mL, for the quantitative DCP assay.

(4) Within-Run Precision:
AFP-L3: Within-run precision studies were performed for the AFP-L3 assay over the reportable range for both Total AFP and AFP-L3% using samples that ranged from 10 to 950 ng/mL in Total AFP concentration and ranged from approximately 6% to 80% in AFP-L3%. The acceptance criterion for percent CV (CV%) was set at "within 10%". With respect to all samples, the CV% results ranged from 0.7% to 1.5% for Total AFP and ranged from 0.3% to 5.6% for AFP-L3%.
DCP: Within-run precision studies were performed for the DCP assay over the reportable range for DCP using samples that ranged from 0.2 to 910 ng/mL in DCP concentration. The acceptance criteria for percent CV (CV%) was set at "within 10%" for DCP across upper reportable range (≥ 1 ng/mL) or "within 15%" for DCP across lower reportable range (< 1 ng/mL). With respect to all samples, the CV% results ranged from 1.1% to 6.7% for DCP.

(5) Total Precision:
AFP-L3: Total precision studies were performed for the AFP-L3 assay over the reportable range for both Total AFP and AFP-L3% using 7 pooled human serum samples and 2 levels of controls. Three of the samples were pooled human serum samples near the clinical decision point and were prepared without spiking with analytes. The samples ranged from 10 to 950 ng/mL in Total AFP concentration and ranged from approximately 6% to 80% in AFP-L3%. The acceptance criterion for percent CV (CV%) was set at "within 10%" for all samples. The results of CV%, measured over 21 days, for all samples ranged from 1.4% to 3.1% for Total AFP and ranged from 0.4% to 6.3% AFP-L3%.

DCP: Total precision studies were performed for the DCP assay over the reportable range using 7 pooled human serum samples and 2 levels of controls. Three of the samples were pooled human serum samples near the clinical decision point and were prepared without spiking with analyte. The samples ranged from 0.2 to 910 ng/mL in

DCP concentration. The acceptance criteria for percent CV (CV%) was set at "within 10%" for DCP across upper reportable range (≥ 1 ng/mL) or "within 15%" for DCP across lower reportable range (< 1 ng/mL). The results of CV%, measured over 21 days, for all samples ranged from 1.3% to 7.9%.

(6) Reproducibility (Instrument to Instrument)
The instrument-to-instrument reproducibility study by using 24 instruments evaluated the precision performance characteristics (between-instrument) for AFP-L3 and DCP assays. The acceptance criterion for percent CV (CV%) was set at "within 10%" for both Total AFP and AFP-L3% and set at "within 10%" for DCP. The results ranged from 1.6% to 2.7% for both Total AFP and AFP-L3% and ranged from 4.9% and 5.6% for DCP.

(7) Recovery
The recovery study evaluated the accuracy of quantitative "AFP-L3" and "DCP" assays. Percent recovery was determined as a percentage of expected value (%: obtained value divided by expected value X 100). The results of recovery (%) ranged from 97.8% to 104.9 % for Total AFP and ranged from 98.1% to 100.9 % for AFP-L3%. The results of recovery (%) ranged from 94.0% to 111.6% for DCP.

(8) Interference
Potential interfering substances were evaluated by determining recovery performance in the presence of known amounts, including concentrations higher than expected in whole blood, of the following substances: Hemoglobin, Bilirubin, Conjugated bilirubin, Triglycerides, Ascorbic acid, Glucose, Galactose, Rheumatoid factor, Vitamin B1, Vitamin B6, Vitamin B12, Ibuprofen, Acetaminophen, Acetylsalicylic acid, IFN-α, IFN-β and IFN-γ. For Total AFP and AFP-L3% assay, no significant effect from the potential interferents occurred. For the DCP assay, no significant effect from the potential interferents occurred. Glucose and galactose were not tested for the DCP assay.

(9) HAMA Interference
Potential inferences of two types of HAMA interferents (Type 1 SQ and Type 2L SQ) were evaluated at concentrations higher than expected in whole blood by determining recovery performance. No significant effect from the HAMA interferents occurred for the Total AFP, AFP-L3%, and DCP assays.

(10) Method Comparison/ Correlation

µTASWako AFP-L3:
A comparison of the µTASWako AFP-L3 to a similar AFP-L3 assay (LBA AFP-L3) was performed using µTASWako i30 and LiBASys, respectively. A comparison study of 200 samples from 100 patients was conducted by both instruments. In addition, 40 serum samples spiked with AFP-L1 and AFP-L3 to cover the upper part of the reportable range were studied.

Deming analysis, excluding two outliers, shows acceptable correlation with and without spiked samples, as demonstrated in the correlation graphs given herein. Correlation #1 shows the Deming regression analysis of AFP-L3% values, with spiked samples and without outliers, run on µTASWako i30 and LiBASys. Correlation #2 shows the Deming regression analysis of AFP-L3% values, without spiked samples and without outliers.

X = LBA AFP-L3 (LiBASys)
Y = µTASWako AFP-L3 (µTASWako i30)

µTASWako AFP-L3 Correlation #1

Number (n)	238
Intercept	0.62, 95% CI (-0.03 to 1.26)
Slope	0.97, 95% CI (0.95 to 0.98)

µTASWako AFP-L3 Correlation #2

Number (n)	198
Intercept	0.78, 95% CI (0.03 to 1.54)
Slope	0.96, 95% CI (0.91 to 1.00)

Using the data from correlation #2 and the clinical cut-off value of 10%, a concordance rate (overall agreement) of 90.4% was found.

µTASWako DCP:

A comparison of the µTASWako DCP to a similar DCP assay (LBA DCP) was performed using µTASWako i30 and LiBASys, respectively. A comparison study of 200 samples from 100 patients was conducted by both instruments. In addition, 20 serum samples spiked with DCP to cover the upper part of the reportable range were studied.

Deming analysis shows acceptable correlation with and without spiked samples, as demonstrated in the correlation graphs given herein. Correlation #1 shows the Deming regression analysis of DCP values, with spiked samples, run on µTASWako i30 and LiBASys. Correlation #2 shows the Deming regression analysis of DCP values, without spiked samples.

X = LBA DCP (LiBASys)
Y = µTASWako DCP (µTASWako i30)

µTASWako DCP Correlation #1

Number (n)	220
Intercept	-0.94, 95% CI (-2.09 to 0.21)
Slope	1.04, 95% CI (1.00 to 1.08)

µTASWako DCP Correlation #2

Number (n)	200
Intercept	0.61, 95% CI (-0.50 to 1.72)
Slope	0.95, 95% CI (0.85 to 1.04)

Using the data from correlation # 2 and the clinical cut-off value of 7.5 ng/mL, a concordance rate (overall agreement) of 95.5% was found.

(11) Stability
Long-term stability and stability after opening (on-board the instrument) were evaluated for the reagent, calibrator set, and two levels of controls for both assays. The results demonstrated stability according to the labeled storage conditions. In addition, during 30 days, stability of one-time instrument calibration using the same container of reagent (opened and stored on-board) was evaluated and found to support use of the same calibration curve.

Rationale for Substantial Equivalence:
Substantial equivalence of µTASWako i30 Immunoanalyzer System as intended for use with the µTASWako AFP-L3 and µTASWako DCP Immunological Test Systems, including the associated calibrators and controls, is determined to be substantially equivalent to the predicates based upon the comparison of intended use/ indications for use, technological characteristics/ technical specifications and the results of performance testing (non-clinical).

The differences that exist arise due to the use of technology that improves the analytical capability for the AFP/AFP-L3% and DCP analytes assayed. These differences do not alter the safety and effectiveness of Subject Device.

Conclusion:
The non-clinical tests performed using the µTASWako i30 Immunoanalyzer System with the µTASWako AFP-L3 and µTASWako DCP Immunological Test Systems, including the associated calibrators and controls, demonstrate that the system is as safe, effective, and performs as well as the legally marketed predicate devices identified above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

MAR 0 1 2011

Wako Chemicals, USA, Inc.
Wako Diagnostics
c/o Martha Murari, Ph.D., RAC
Manager, Regulatory Affairs
1025 Terra Bella Ave, Suite A
Mountain View, CA 94043

Re: k100464
Trade/Device Name: Wako μTASWako AFP-L3 Immunological Test System
Wako μTASWako DCP Immunological Test System
Wako μTASWako i30 Immunoanalyzer System
Wako μTASWako AFP-L3 Calibrator Set
Wako μTASWako AFP-L3 Control L and Control H
Wako μTASWako DCP Calibrator Set
Wako μTASWako DCP Control L and Control H
Regulation Number: 21CFR§866.6030
Regulation Name: AFP-L3% Immunological Test System
Regulatory Class: Class II
Product Code: NSF, OAU, OUE, JIT, JJX
Dated: February 14, 2011
Received: February 15, 2011

Dear Dr. Murari:

This letter corrects our substantially equivalent letter of February 23, 2011.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.html.

Sincerely yours,

Maria M. Chan, Ph.D
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K100464

Device Name: Wako μTASWako AFP-L3 Immunological Test System and Wako μTASWako DCP Immunological Test System

Indications for Use for μTASWako AFP-L3 Immunological Test System:
The μTASWako AFP-L3 Immunological Test System is an *in vitro* device that consists of reagents used with the μTASWako i30 Immunoanalyzer to quantitatively measure, by immunochemical techniques, AFP-L3% in human serum. The device is intended for *in vitro* diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma (HCC) in conjunction with other laboratory findings, imaging studies and clinical assessment. Patients with elevated AFP-L3% values (≥ 10%) have been shown to be associated with an increase in the risk of developing HCC within the next 21 months and should be more intensely evaluated for evidence of HCC according to the existing HCC practice guidelines in oncology.

Indications for Use for μTASWako DCP Immunological Test System:
The μTASWako DCP Immunological Test System is an *in vitro* device that consists of reagents used with the μTASWako i30 Immunoanalyzer to quantitatively measure, by immunochemical techniques, DCP in human serum. The device is intended for *in vitro* diagnostic use as an aid in the risk assessment of patients with chronic liver disease for development of hepatocellular carcinoma (HCC) in conjunction with other laboratory findings, imaging studies, and clinical assessment.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Reena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k100464

Indications for Use

510(k) Number (if known): K100464

Device Name: Wako μTASWako i30 Immunoanalyzer

The μTASWako i30 Immunoanalyzer is an *in vitro* diagnostic automated instrument intended for use to quantitatively measure analytes in clinical chemistry by immunochemical techniques. The μTASWako i30 Immunoanalyzer is indicated for use by healthcare professionals. It is intended for assays cleared or approved for use on this instrument.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Reena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k100464

Indications for Use

510(k) Number (if known): K100464

Device Name: Wako μTASWako AFP-L3 Calibrator Set,
Wako μTASWako AFP-L3 Control L, and
Wako μTASWako AFP-L3 Control H

The Wako μTASWako AFP-L3 Calibrator Set is designed to be used with the Wako μTASWako AFP-L3 Immunological Test System for the quantitative determination of AFP-L3% in human serum.

The Wako μTASWako AFP-L3 Control L is designed to be used as quality control material for the quantitative determination of AFP-L3% in human serum using the Wako μTASWako AFP-L3 Immunological Test System.

The Wako μTASWako AFP-L3 Control H is designed to be used as quality control material for the quantitative determination of AFP-L3% in human serum using the Wako μTASWako AFP-L3 Immunological Test System.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Leena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100464

Indications for Use

510(k) Number (if known): K100464

Device Name: Wako μTASWako DCP Calibrator Set,
Wako μTASWako DCP Control L, and
Wako μTASWako DCP Control H

The Wako μTASWako DCP Calibrator Set is designed to be used with the Wako μTASWako DCP Immunological Test System for the quantitative determination of DCP in human serum.

The Wako μTASWako DCP Control L is designed to be used as a quality control material for the quantitative determination of DCP in human serum using the Wako μTASWako DCP Immunological Test System.

The Wako μTASWako DCP Control H is designed to be used as a quality control material for the quantitative determination of DCP in human serum using the Wako μTASWako DCP Immunological Test System.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K100464